EXHIBIT C

PARRISH LAW OFFICES

788 Washington Road
Pittsburgh, Pennsylvania 15228-2021
www.dparrishlaw.com

412.561.6250
Fax 412.561.6253
E-mail: info@dparrishlaw.com

March 26, 2019

VIA PRIORITY MAIL
DHHS – OMHA
Centralized Docketing
Attn: Beneficiary Mail Stop
200 Public Square, Suite 1260
Cleveland, OH 44114-2316

BENEFICIARY APPEAL

RE: Request for ALJ Hearing
Beneficiary: David Christenson
5754 Clevedon Lane
Oshkosh, WI 54904

HICN: 7QR9QM0QP33
Device: Tumor Treatment Field Therapy (E0766)
Supplier: Novocure, Inc.

Dates of Service: 5/3/2018; 6/3/2018; 7/3/2018
Medicare Appeal No: 1-8277865244
Date of QIC Decision: March 12, 2019
Our Ref: 19-137

Dates of Service: 8/3/2018; 9/3/2018; 10/3/2018
Medicare Appeal No: 1-8290080476
Date of QIC Decision: March 19, 2019
Our Ref: 19-138

Dear Claims Coordinator:

As an authorized representative of the above-captioned Medicare beneficiary, David Christenson, I hereby appeal to an Administrative Law Judge the above-captioned decision rendered by the Qualified Independent Contractor ("QIC") C2C Innovative Solutions, Inc. for the claims submitted for tumor treatment field therapy ("TTFT") for a glioblastoma. The QIC rendered a nonsensical denial stating "the medical documentation of the efficacy of this device is not within the usual scope and breath (sic) of current medical literature with peer acknowledgement and review." The QIC also asserts that although the DMACs acknowledged a valid reconsideration request was filed, LCD L34823 remains applicable until the DMACs retire it or issue a new LCD.

Mr. Christenson is a Medicare beneficiary who has been married for 41 years. He has two children and two grandchildren. He was diagnosed with a glioblastoma in 2016. He had

surgery and was treated with radiation and chemotherapy. His clinician also prescribed TTFT and began using it in October 2016. TTFT disrupts and corrupts the division of cancer cells and leads to the death of such cells. In 2011 and 2015, the FDA approved, through its more rigorous review process, a device to deliver TTFT, finding it to be safe and effective for the treatment of glioblastomas. During the clinical trial for newly diagnosed glioblastomas and a first recurrent, such as that of Mr. Christenson, the TTFT results were so compelling that at the interim analysis, the Data Safety Monitoring Board recommended that those not receiving TTFT be able to cross over to receive the treatment. The FDA agreed.

The published, peer-reviewed literature shows the improved clinical survival and the progression-free survival of patients who receive TTFT for their glioblastoma. TTFT for glioblastoma is included in the National Comprehensive Cancer Network ("NCCN") guidelines and is considered the standard of care for newly diagnosed glioblastoma. Hundreds of treating physicians, in all 50 states, have prescribed TTFT. TTFT is covered by all the large national payers. Medicare has paid for numerous claims for medically indistinguishable beneficiaries.

The QIC's determination does not make sense. The seminal articles showing the effectiveness of the treatment/device were published in JAMA, one of the most prestigious journals in the country based on "impact factor." JAMA is a peer-reviewed publication, thus the assertion that the documentation lacks review is belied by the evidence. Multiple peer-reviewed articles show the effectiveness of the device, to the QIC's comment regarding scope and breadth. The inclusion of TTFT in the NCCN guidelines is "peer acknowledgment and review."

With respect to the LCD, the enclosed documents show that the LCD has not kept pace with the current peer-reviewed literature, regulatory status, consensus of experts, scientific evidence or adoption by the relevant medical community. Indeed, the LCD record shows that the DMACs have failed to update the LCD to reflect consideration of developments that have occurred over the past five years. As noted in the QIC decision, an LCD which conflicts with the standard of care must be "based on sufficient evidence to convincingly refute evidence presented in support of coverage." No such evidence exists.

Yours very truly,

Debra M. Parrish/TMT

Debra Parrish on behalf of
Mr. David Christenson

Enclosures:
Attachment A: Appointment of Representative Form
Attachment B: Certificate of Service
Attachment C: LCD List of Exhibits

cc: Mr. David Christenson
Novocure, Inc., c/o Justin Kelly

PARRISH LAW OFFICES

788 Washington Road
Pittsburgh, Pennsylvania 15228-2021
www.dparrishlaw.com

412.561.6250
Fax 412.561.6253
E-mail: info@dparrishlaw.com

April 10, 2019

VIA PRIORITY MAIL

Judge Richard Zettel
Office of Medicare Hearings and Appeals
Cleveland Field Office
200 Public Sq., Suite 1300
Cleveland, OH 44114-2316

RE: Prehearing Brief
ALJ Appeal Nos. 1-8416229632 & 1-8416270832
Appellant/Beneficiary: D. Christenson
Service: E0766
Dates of Services: 5/3/18, 6/3/18, 7/3/18, 8/3/18, 9/3/18, 10/3/18
Hearing Date: TBD
Our Ref. No.: 19-137 & 19-138

Dear Judge Zettel:

In anticipation of the scheduling of the above-captioned case, please find attached a prehearing brief to aid in your analysis. We have compiled (1) additional studies from 2018 and 2019 and (2) textbook chapters from medical textbooks since the filing of the underlying reconsideration request for these consolidated cases, which are included on the attached CD. The LCD Record Exhibit List referenced in the brief was appended to the request for hearing.

If you have any questions regarding the foregoing, please do not hesitate to contact me at (412) 561-6250. We appreciate your consideration.

Respectfully submitted,

Debra M. Parrish
Attorney for D. Christenson

Enclosures:

Attachment A: Prehearing Brief
Attachment B: CD containing:
-TTFT bibliography for GBM & additional peer-reviewed studies from 2018 & 2019 - (aside from those previously submitted with the reconsideration request)
-Medical school textbook excerpts

cc: Mr. D. Christenson